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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,121	12/23/2004	Marc K. Hellerstein	416272003900(PATENT)	4870

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/519,121	Applicant(s) HELLERSTEIN, MARC K.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119.

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled high density lipoprotein (HDL) particles are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein an isotopically labeled bile acid is administered in a different manner than the isotopically labeled high density lipoprotein (HDL) particles when determining the rate of the second arm of reverse cholesterol transport.

Group II, claim(s) 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol molecules are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein an isotopically labeled bile acid is administered in a different manner than the isotopically labeled cholesterol molecules when determining the rate of the second arm of reverse cholesterol transport.

Group III, claim(s) 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol precursors are

administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein an isotopically labeled bile acid is administered in a different manner than the isotopically labeled cholesterol precursors when determining the rate of the second arm of reverse cholesterol transport.

Group IV, claim(s) 1-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled high density lipoprotein (HDL) particles are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein the isotopic label of an isotopically labeled bile acid is different than the isotopic label of the isotopically labeled high density lipoprotein (HDL) particles when determining the rate of the second arm of reverse cholesterol transport.

Group V, claim(s) 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol molecules are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein the isotopic label of an isotopically labeled bile acid is different than the isotopic label of the isotopically labeled cholesterol molecules when determining the rate of the second arm of reverse cholesterol transport.

Group VI, claim(s) 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol precursors are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein the isotopic label of an isotopically labeled bile acid is

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different than the isotopic label of the isotopically labeled cholesterol precursors when determining the rate of the second arm of reverse cholesterol transport.

The inventions listed as Groups I- VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical features linking the inventions of Groups I-VI are the administration of isotopically labeled molecules to a living system, and the administration of different types of isotopically labeled molecules in a different manner or with a different label. However, these technical features are obvious or anticipated over Scheibner J. et al. (Complex feedback regulation of bile acid synthesis in the hamster: the role of newly synthesized cholesterol. *Hepatology*. 1999 Jul;30(1):230-7), and therefore do not constitute special technical features as defined by PCT Rule 13.2, because they do not define a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

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inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


3/30/06